

Central Pennsylvania Eye and Ear
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Hearing Director

8115 '00 OCT 19 P1:57

October 5, 2000

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, SW
Room 615F
Washington, D.C. 20201

Dear Secretary Shalala,

As a small business owner and spouse of a hearing health care provider, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underused medical devices.

I am very concerned about reports that the Food and Drug Administration has reportedly sent you a proposal for revising the current regulations regarding the dispensing of hearing aids that would both dramatically increase the cost of hearing health services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule would have on the nation's hearing impaired and on the nation's many small business hearing aid specialists. Please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act. We are concerned that no one group of hearing healthcare providers is determined to be gatekeepers, thereby forcing other hearing health care providers to close down their small businesses.

Hearing impairment is a major health concern. Please do not let the FDA propose any regulations that would limit the number of hearing health care providers, force others out of business, and thereby both limit access and dramatically increase the cost of hearing health care for the estimated 28 million Americans with a hearing impairment.

Very truly yours,

Robert L. Kardos, O.D.

Robert L. Kardos, OD

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Eye
Examinations

Hearing
Examinations

Adult and
Pediatric

Eyeglasses

Contact Lenses

Hearing Aids

Vision Training

Sports Vision

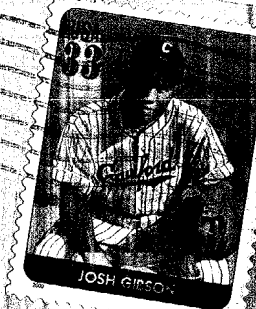
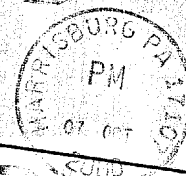
Low Vision
Devices

Computerized
Testing Equipment

Safety Glasses



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